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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,077	03/24/2004	Mark Tsonton	END-5294	7100
27777 PHILIP S. JOH	7590 03/18/200 <b>NSON</b>	EXAMINER		
JOHNSON & J		LEE, EDMUND H		
ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003		1	ART UNIT	PAPER NUMBER
			1791	
			MAIL DATE	DELIVERY MODE
			03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/808,077	TSONTON ET AL				
Office Action Summary	Examiner	Art Unit				
	EDMUND H. LEE	1791				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>07 De</u>	ecember 2007					
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<i>,</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-6,8-10 and 16-24</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-6,8-10 and 16-24</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement					
are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ acce	epted or b) $\square$ objected to by the E	Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some coll None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) X Notice of References Cited (PTO-892)	4) 🔲 Interview Summary					
2) DNotice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ite				
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  Other:						
1	,					

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## **DETAILED ACTION**

1. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite because it is dependent upon itself. It appears that it should be dependent upon claim 17.

Correction is required.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1,2,3,5,6,8,9,10,16,21,22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Truckai et al (USPN 6485436). Truckai et al teach the claimed process as evidenced at col 3, lns 40-58; and figs 2A and 4.
- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. In order to expedite prosecution, indefinite claim 18 has been interpreted as being dependent upon claim 17.
- 6. Claims 4,17,18,19,20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai et al (USPN 6485436). The above teachings of Truckai et al

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are incorporated hereinafter. In regard to claim 4, Truckai et al teach molding the outer sleeve by molding. Though injection molding is not specifically taught by Truckai et al. such is well-known in the molding art as an effective and efficient means for molding. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to injection mold the outer sleeve/distal segment of Truckai et al in order to produce the sleeve with quickness and accuracy. In regard to claims 17 and 18, Truckai et al teach forming the outer sleeve by casing and providing an outer sleeve having a traverse tissue receiving port. Though Truckai et al does not teach using two halves joined together to form the distal needle segment and tissue receiving port, it is well-known in the molding and casing art to form a designed sleeve by joining two halves. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the outer sleeve/distal segment of Truckai et al by joining two halves in order to simplify the assembly process. In regard to claim 19-20, such is well-known in the biopsy needle art in order to easily provide for an MRI artifact. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to design the closed tip of Truckai et al to have the claimed features in order to easily provide an MRI artifact. In regard to claim 23, the use of a specific material is a mere obvious matter of choice dependent on the desired final product and of little patentable consequence to the claimed process since it is not a manipulative feature or step of the claimed process. Further, the claimed material is well-known in the needle art. Thus, it would have been obvious to one of ordinary skill

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in the art at the time the invention was made to use the claimed material in the process of Truckai et al in order to ensure a durable needle.

- 7. Applicant's arguments with respect to claims 1-6,8-10, and 16-24 have been considered but are most in view of the new ground(s) of rejection.
- 8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPN 6626849 teaches a biopsy needle formed from joined halves, and a closed tip providing an MRI artifact.
- 9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDMUND H. LEE whose telephone number is

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571.272.1204. The examiner can normally be reached on MONDAY-THURSDAY

FROM 9AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Christina Johnson can be reached on 571.272.1176. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDMUND H. LEE Primary Examiner

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**EHL** 

/EDMUND H. LEE/

Primary Examiner, Art Unit 1791